## REMARKS

Claims 1, 4-9, 11-23, 25-28, 76-77, and 142-163 are currently pending in the above-identified patent application and remain for consideration. Claims 10 and 24 are cancelled by this amendment. Claims 2-3, 29-75, and 78-141 were previously cancelled.

Claims 1, 4-14, 26-28, and 142-163 were rejected under the second paragraph of 35 U.S.C. § 112, allegedly for indefiniteness.

Claims 17-23 and 76-77 were rejected under the first paragraph of 35 U.S.C. § 112, allegedly for lack of compliance with the written description requirement.

Claims 76-77 and 162-163 were rejected under the first paragraph of 35 U.S.C.§ 112, allegedly for lack of compliance with the enablement requirement.

Claims 15-16, 76-77, 142-157, and 159-163 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Kato et al. (WO/00/00506, previously cited) ("KATO").

Claims 142, 157 and 158 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over KATO in view of U.S. Patent No. 5,932,210 (Gregory et al.).

Claims 24-25 were objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Reexamination of the application as amended, reconsideration of the rejections and objections, and allowance of the claims remaining for consideration are respectfully requested.

The deadline for response to this final Office Action has been extended until September 7, 2006 by the filing of a three-month Request for Extension of Time Under 37

C.F.R. § 1.136(a) together with this response. Therefore, this response is being filed in a timely manner.

## I. AMENDMENTS TO THE CLAIMS

Entry of the amendments to the application is respectfully requested. As detailed below, the amendments introduce no new matter.

The amendments to existing claims are made for clarity and definiteness of the claimed invention. Amendments to claims 1, 11, 14, 17, 26-28, 76, and 142 should obviate Examiner's rejections under 35 U.S.C. § 112, first and second paragraphs. Specifically, claim 1 has been amended according to Examiner's suggestion to specify a sequence that is 95% or more identical to SEQ ID NO: 1, removing the limitation that the sequence is distinct from SEQ ID NO: 37. Support for claim 1 as amended is found in the specification on p. 3, par.2, among other places. Claims 4-14 are dependent on claim 1 and therefore are fully supported by the specification as well. The aforementioned amendments introduce no new matter.

Claim 11 has been amended according to Examiner's suggestion to remove the reference to a subsequence that is at least 25 base pairs long. Support for claim 11 as amended is found in the specification on p.3, par. 3, among other places. This amendment introduces no new matter.

Claim 17 has been amended to specify that the polynucleotide sequence encodes a polypeptide that inhibits apoptosis. Support for claim 17 as amended is found in the specification on p.3, par. 5 and p.39, par. 3, among other places. Claims 18-23 are dependent on claim 17 and therefore are fully supported by the specification as well. The aforementioned amendments introduce no new matter.

Claim 24 has been canceled to avoid duplication, since amended claim 17 includes all of the limitations of claim 24. Claim 25 has been amended to depend from claim 17 as opposed to canceled claim 24. This amendment introduces no new matter.

Claim 142 has been amended to specify that the recited polypeptide is encoded by the isolated or recombinant nucleic acid of this claim. This amendment is supported by the specification and introduces no new matter.

Amendments to claims 26-28 and 159-161 should obviate Examiner's rejections under 35 U.S.C. § 101 for non-statutory subject matter. Specifically, claim 26 has been amended to specify an isolated transformed cell as suggested by the Examiner. Support for claim 26 as amended is found in the specification on p.34, par. 3, among other places. Claims 27 and 28, which are dependent on claim 26, have been similarly amended and are fully supported by the specification. Claim 159 has been amended to specify an isolated transformed cell as suggested by the Examiner. Claims 160 and 161, which are dependent on claim 159, have been similarly amended and are fully supported by the specification. The aforementioned amendments introduce no new matter.

Amendments to claims 15-16, 76-77, and 142-163 should obviate Examiner's rejections under 35 U.S.C. §§ 102(b) and 103. Specifically, claim 15 has been amended to specify that the sequence is greater than 700 base pairs in length. Support for claim 15 as amended can be found in the specification on p.30, pars. 1 and 4, among other places. Claim 16 is dependent upon claim 15 and therefore is supported by the specification as well. The aforementioned amendments introduce no new matter.

Claim 76 has been amended to specify that the sequence is at least 90% identical to SEQ ID NO:2, also specify that the sequence is greater than 700 base pairs in length, and further specify that the sequence encodes a polypeptide that inhibits apoptosis. Support for claim 76 as amended can be found in the specification p.30, pars. 1 and 4, among other places. Claim 77 has been amended according to the Examiner's suggestion to remove a limitation that the nucleic acid is expressed in a cell in vivo. The aforementioned amendments introduce no new matter.

Claim 142 has been amended to specify that the sequence is greater than 700 base pairs in length. Support for claim 142 as amended can be found in the specification p.30, pars. 1 and 4, among other places. Claims 143-163 are dependent on claim 142 and therefore are supported by the specification as well. The aforementioned amendments introduce no new matter.

Claim 163 is amended to delete the reference to in vivo expression. This amendment introduces no new matter.

Applicant wishes to thank the Examiner for suggesting possible claim amendments in the recent Office Action and in the telephonic interview held on August 25, 2006. Applicant further thanks the Examiner for the courtesy of that interview.

This response is being filed in accordance with recently revised 37 C.F.R. § 1.121, as set forth in 68 F.R. 38611 (June 30, 2003). If the amendment is considered to be not in compliance with recently revised 37 C.F.R. § 1.121, the Examiner is respectfully requested to contact the undersigned at his earliest possible convenience.

## II. CLAIM REJECTIONS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

Claims 1, 4-14, 26-28, 142-163 have been rejected under 35 U.S.C. § 112, second paragraph, for allegedly failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

The Examiner rejected claim 1 and claims dependent thereupon because the limitation that the sequence is distinct from SEQ ID NO: 37 allegedly renders the claim indefinite. The Examiner rejected claim 11 and claims dependent thereupon because the limitation that the subsequence is at least 25 base pairs long allegedly renders the claim indefinite. The Examiner rejected claim 26 and claims dependent thereupon because the limitation directed to any nucleic acid of claim 1 allegedly lacks sufficient antecedent basis. The

Examiner rejected claim 142 and claims dependent thereupon because reference to the polypeptide allegedly lacks sufficient antecedent basis.

Applicant's amendments to the claims should obviate the above rejections. In addition, Applicant respectfully wishes to traverse Examiner's rejections under 35 U.S.C. § 112, second paragraph, as follows.

Definiteness of a claim under 35 USC §112, second paragraph is a determination of whether the claim is reasonably clear and precise when analyzed in light of: (A) the content of the application; (B) the teachings of the prior art; and (C) the claim interpretation that one ordinarily skilled in the art would give to the claim. (*In re Moore*, 439 F.2d 1232 (CCPA 1971)).

Claim 1 has been amended as suggested by the Examiner to specify a sequence that is 95% or more identical to SEQ ID NO: 1. This amendment clarifies the Applicant's intent and should put claim 1 in compliance with written description requirements.

Claim 11 has been amended as suggested by the Examiner to remove the limitation that the subsequence is at least 25 base pairs.

Claim 26 has been amended to read the nucleic acid as suggested by the Examiner. This amendment obviates Examiner's earlier concern that the limitation lacked sufficient antecedent basis.

Claim 142 has been amended to clarify that the term polypeptide refers to a polypeptide encoded by the isolated or recombinant nucleic acid of this claim. This amendment obviates Examiner's earlier concern that the limitation lacked sufficient antecedent basis.

Applicant thanks the Examiner for suggesting possible claim amendments in an effort to further the prosecution of this case.

In light of the above remarks, Applicant respectfully submits that the rejections under 35 USC §112, second paragraph have been addressed, and respectfully requests that the Examiner withdraw these rejections and allow the claims.

## III. CLAIM REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

Claims 17-23, 76 and 77 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner rejected claims 17-23 because the claims allegedly do not indicate that the sequence encodes a polypeptide with a specific function. The Examiner stated that claims 17-23 encompass variants of SEQ ID NO:1 that although they are at least 95% identical to SEQ ID NO: 1 they may encode non-functional variants or variants with a completely different function. The Examiner rejected claims 76-77 because the claims allegedly encompass nucleic acid sequences that encode polypeptides that are at least 65% identical to SEQ ID NO: 2; however, the claims allegedly do not indicate that encoded polypeptide has any specific function.

Applicant's amendments to the claims should obviate the above rejections.

In addition, Applicant respectfully wishes to traverse the Examiner's rejections under 35 U.S.C. § 112, first paragraph, as follows.

Claim 17 has been amended to specify that the recited polypeptide of this claim inhibits apoptosis. This amendment clarifies that the encoded polypeptide has a specific function, namely inhibiting apoptosis. Therefore, claim 17 as amended and claims dependent thereupon meet written description requirement.

Claim 76 has been amended to specify that the recited polypeptide of this claim inhibits apoptosis. This amendment clarifies that the encoded polypeptide has a specific function, namely inhibiting apoptosis. Therefore, claim 76 as amended and claims dependent thereupon meet written description requirements.

Claims 76, 77, 162 and 163 have also been rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement. This rejection was made because the specification, while being enabling for a method for producing a polypeptide in solution or in vitro, allegedly does not reasonably provide enablement for a method of producing a polypeptide in vivo. The Examiner stated that the specification allegedly does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Amendments to claims 76 and 142 should obviate Examiner's rejections on grounds of alleged lack of enablement. Applicant respectfully notes that claims 162 and 163 depend on claim 142, thus amendment of claim 142 should obviate Examiner's alleged lack of enablement rejections with respect to claims 162 and 163.

Although the above-referenced amendments should obviate Examiner's rejection of claims 76, 77, 162 and 163 as allegedly lacking enablement under 35 U.S.C. § 112, first paragraph, in addition Applicant respectfully wishes to traverse Examiner's rejections below.

It is established that the following factors have to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph: (1) the quantity of experimentation necessary; (2) the amount of direction or guidance presented; (3) the presence or absence of working examples; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *In re Wands*, 8 USPQ 2d 1400 (CAFC 1988).

Examiner has only discussed *In re Wands* factors (4), (7), and (8) in the Examiner's argument following rejection of claims 76, 77, 162 and 163 as allegedly lacking enablement. Since the Examiner did not discuss any additional *In re Wands* factors apart from the ones mentioned above, Applicant respectfully believes that all remaining factors speak in Applicant's favor and thus should not be further addressed.

The nature of the invention

Examiner has stated that the claims at issue allegedly encompass making a polypeptide in vivo and encompass making the polypeptide as a therapeutic polypeptide in vivo, which allegedly encompasses gene therapy.

Applicant respectfully disagrees with the Examiner's classification of the pertinent claims as encompassing the unpredictable art of gene therapy. Applicant also respectfully wishes to point out to the Examiner that the pertinent claims do not recite the limitation that the produced polypeptide is a therapeutic polypeptide. This limitation is absent from the above claims, and the above claims are not limited to making the polypeptide in vivo, since they also encompass polypeptide production in a solution or in a cell in vitro. In short, these are not therapeutic claims.

Moreover, Applicant respectfully states that the above claims as they relate to producing a polypeptide in a cell in vivo are similarly fully enabled by the specification. Applicant respectfully disagrees with the Examiner's classification of the pertinent claims as falling within the art of gene therapy. Practitioners of reasonable skill in the art understand the term "gene therapy" to mean replacement of a defective gene. Applicant's claims are directed to producing a polypeptide in vivo and not replacing a defective gene.

Moreover, the fact that an invention may be potentially classified in the art of gene therapy is not a bar to patentability per se. It is well established that the art of gene therapy has advanced tremendously in the last few years, which is further evidenced by scientific publications on the topic, as well as by an ever-increasing number of issued patents encompassing gene therapy type claims.

The breadth of the claims

The Examiner has stated that the instant claims are allegedly broad in the sense that the steps merely recite a method of producing a polypeptide comprising expressing a nucleic

acid encoding an amino acid sequence ... wherein the nucleic acid is expressed in vivo. Examiner has further stated that given their broadest reasonable interpretation consistent with the specification, the claims encompass expressing the polypeptide in order to treat a disease. However, as emphasized above, these claims are not therapeutic claims.

Applicant believes that the amended claims fully meet the requirements of enablement under 35 U.S.C. § 112, first paragraph. In addition, Applicant respectfully responds that the claims are fully supported by the specification and not unduly broad. Currently introduced amendments to claims 76, 77, 162 and 163 further define the claim scope by specifying that the amino acid encodes a polypeptide that encodes apoptosis. Therefore, Applicant respectfully submits that the claims as currently amended are of fairly limited scope and in full compliance with the enablement requirements of 35 U.S.C. § 112, first paragraph.

The unpredictability of the art and the state of the prior art

The Examiner has stated that the specification allegedly does not disclose that the methods have effectively treated any disease or disorder by administering a nucleic acid which encodes the protein and expressing the protein in vivo in order to obtain a therapeutic effect. Examiner has further stated that at the time of filing, the relevant art considered gene therapy to be allegedly unpredictable. Examiner has proceeded to cite the **Anderson (1998)** reference in support of the allegation that the art of gene therapy is unpredictable. Examiner has proceeded to cite the **Dang et al. (1999)** reference in support of the allegation that the major challenge that limits clinical applications of gene therapy remains in achieving efficient gene delivery to target tissues. Furthermore, Examiner has stated that the claimed method can be allegedly interpreted as treating any disease associated with an abnormally high level of apoptosis such as diabetes by administering a polynucleotide encoding the anti-apoptotic polypeptide to a diabetic patient. Examiner has cited the **Levine (1999)** reference in support of the allegation that gene therapy for diabetes is unpredictable. Examiner has concluded that the specification allegedly does not disclose working examples or provide guidance which would overcome the art-recognized problems.

Applicant respectfully wishes to traverse Examiner's rejections below. The Examiner is well aware that the present application was filed in 2002, therefore state of the prior art should be established as of the filing date. It is similarly established that the art of gene therapy and genetic engineering has made tremendous progress in the last few years. Therefore, many of the problems and hurdles represented by the **Anderson**, **Dang et al.**, and **Levine** were solved by the time the present application was filed in 2002. For example, present specification discloses multiple working examples of nucleic acids, polypeptides, antibodies, host cells, transcription control elements, vectors, routes of administration, and delivery vehicles suitable for practicing the invention. In addition, the specification incorporates by reference a variety of protocols, laboratory manuals and scientific publications relating to the current invention and providing guidance as to the invention. The specification also provides working examples using the claimed native sequences, as well as mutations, deletions, fusions, chimerics and recombinants thereof.

The Examiner has stated that the specification allegedly does not disclose that the methods of the present invention have effectively treated any disease or disorder. Applicant respectfully wishes to respond that this statement is tantamount to demanding that clinical data be present in the specification. However, it is established that enablement requirements under 35 U.S.C. § 112, first paragraph, do not require inclusion of clinical data. Moreover, it is similarly established that the unpredictability of a particular art is not a per se bar to patentability. While an art may be unpredictable, particular enabled embodiments, such as the ones disclosed in the instant claims, are patentable.

The Examiner has stated that allegedly additional experimentation would be required in order to practice the invention to the full scope encompassed by the claims. Applicant respectfully notes that the quantity and level of experimentation required is not excessive in view of the subject matter. Methods for the synthesis and comparison of nucleic acid sequences are well understood in the art. Moreover, and as discussed above, the specification teaches the structures and functions of the invention polynucleotides and polypeptides. When these methods are combined with the teachings of the specification, there is

little experimentation to be carried out by one of ordinary skill in the art. What experimentation is required is routine in view of the well-understood nature of the methods.

Applicant respectfully submits that the current specification provides sufficient guidance as to the invention, both structurally and functionally. The specification also directs a practitioner of reasonable skill in the art to numerous sources for understanding the invention and the methodologies employed therewith. Moreover, one ordinarily skilled in the art of molecular biology will have a substantial understanding of these and other methodologies. Reading the claims in light of the specification provides adequate definition to these claims, allowing one of ordinary skill in the art to make and use the claimed invention without undue experimentation. In light of the above remarks, Applicant therefore respectfully submits that the invention of the current claims is enabled and asks that the Examiner withdraw this rejection.

## IV. CLAIM REJECTIONS UNDER 35 U.S.C. § 101

The Examiner has rejected claims 26-28 and 159-161 under 35 U.S.C. § 101 because the claimed invention is allegedly directed to non-statutory subject matter. Examiner has stated that the instant claims are not limited to an isolated cell and as such encompass a transformed cell that is present in a human.

Applicant respectfully thanks the Examiner for suggesting amendments to comply with the statutory subject matter requirement of 35 U.S.C. § 101. According to the Examiner's suggestion, claims 26-28 and 159-161 are currently amended to specify an isolated transformed cell. In light of the current amendments which obviate Examiner's previous rejection, Applicant respectfully requests the Examiner to withdraw the above rejections and allow the claims.

## V. CLAIM REJECTIONS UNDER 35 U.S.C. § 102

The Examiner has rejected claims 15, 16, 76, 77, 142-157 and 159-163 under 35 U.S.C. § 102(b) as allegedly being anticipated by Kato et al. (WO/00/00506, previously cited) ("KATO"). The Examiner has stated that the sequence of KATO allegedly teaches an isolated

nucleic acid sequence (see SEQ ID NO: 23 of KATO) that is 1168 nucleotides in length. Examiner has further stated that nucleotides 1-700 of KATO's sequence is allegedly 100% identical to nucleotides 74-774 of instant SEQ ID NO: 1. The Examiner has proceeded to conclude that the sequence taught by KATO is encompassed by and anticipates claims 15 and 16 because it would allegedly hybridize to instant SEQ ID NO: 1 under stringent hybridization conditions and because it is in the range of 1000-2500 nucleotides in length.

The Examiner has stated that KATO's sequence allegedly comprises a polynucleotide sequence of instant SEQ ID NO: 1, specifically nucleotides 74-774 of SEQ ID NO: 1. The Examiner has further stated that KATO allegedly also teaches that the sequence can be attached to a "gene chip" or other support. Examiner has also stated that KATO allegedly teaches an expression vector, a promoter, and a bacterial or a eukaryotic host cell. Examiner has proceeded to conclude that KATO allegedly anticipates claims 76, 77 as well as 142-157 and 159-163 of the present invention.

The Applicant's amendments to the claims should obviate the above rejections. In addition, Applicant respectfully wishes to traverse Examiner's rejections under 35 U.S.C. § 102(b) as follows.

It is established that a prior art generic disclosure does not anticipate or make obvious a claim to a species within a particular genus when the prior art generic disclosure does not provide sufficient guidance to select the claimed species from a large number of species within that genus. *See In re Baird*, 16 F.3d 580, 29 USPQ 2d 1550 (Fed. Cir. 1994) (stating that no anticipation or obviousness for a claim to a specific bisphenol derivative in view of prior art disclosing a generic formula that encompasses that specific bisphenol derivative); *In re Bell*, 991 F.2d 781, 26 USPQ 2d 1529 (Fed. Cir. 1993) (holding claims directed to nucleic acid molecules containing human sequences encoding human insulin-like growth factors patentable despite prior art that suggested a vast number of possible nucleic acid sequences, but gave no indication as to the actual human sequence corresponding to the insulin-like growth factor gene).

Claim 15 has been amended to specify a sequence greater than 700 base pairs in length. Claims 16, 76, and 142 have been amended likewise. Claim 77 is dependent on currently amended claim 76 and claims 143-163 are dependent on currently amended claim 142. In light of the current amendments, once the length of the claimed sequences exceeds 700 base pairs, there is absolutely no guidance whatsoever in KATO regarding the sequence of the other base pairs. The number of possible sequences increases geometrically with increasing length of the sequences, once such number exceeds 700 base pairs. However, KATO provides no guidance whatsoever for determining what the additional bases, other than the 700 base pairs actually specified, should be.

In the instant case, a large genus does not necessarily anticipate a relatively small number of species within the genus if there is no guidance for the selection of those species from the large genus. For sequences longer than 700 base pairs, KATO provides no guidance for selecting the correct sequences from the large genus of possible sequences larger than 700 base pairs.

In light of the above amendments and remarks, Applicant respectfully believes that the claims as currently amended meet all requirements of 35 U.S.C. § 102(b). Therefore, Applicant respectfully requests that the Examiner withdraw the above rejections and allow claims 15, 16, 76, 77, 142-157 and 159-163.

## VI. CLAIM REJECTIONS UNDER 35 U.S.C. § 103

The Examiner has rejected claims 142, 157 and 158 under 35 U.S.C. § 103(a) as allegedly being unpatentable over KATO in view of U.S. Patent No. 5,932,210 (Gregory et al.)

Examiner has stated that KATO allegedly teaches an isolated sequence that comprises a sequence that is 100% identical to nucleotides 76-774 of instant SEQ ID NO: 1. Examiner has further stated that KATO does not teach a viral vector that is an adenovirus, however, Gregory et al. allegedly teaches a viral vector that is an adenovirus expression vector that can be used to express a gene of interest in a transformed host cell. The Examiner has

concluded that it allegedly would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of KATO and Gregory et al. to create an adenovirus expression vector that encodes as expressed the nucleic acid taught by KATO in a transformed host cell with a reasonable expectation of success. Examiner has further stated that the motivation to combine the references to create claimed invention is allegedly provided by both KATO and Gregory et al. as KATO allegedly teaches that it is desirable to express the nucleic acid in a transformed host cell using a viral vector and Gregory et al. teaches a specific adenovirus expression vector that can be used to accomplish the expression of the nucleic acid in a transformed host cell.

Applicant's amendments to the claims should obviate the above rejections. In addition, Applicant respectfully wishes to traverse Examiner's rejections under 35 U.S.C. § 103(a) as follows.

When applying the obviousness analysis of 35 U.S.C. § 103(a), the following factors should be examined: (a) the claimed invention must be considered as a whole; (b) the references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination; (c) the references must be viewed without the benefit of impermissible hindsight vision accorded by the claimed invention; and (d) reasonable expectation of success is the standard with which obviousness is determined. *Hodosh v. Block Drug Co., Inc.*, 786 F.2d 1136, 1143 n.5, 229 USPQ 182, 187 n.5 (Fed. Cir. 1986).

When considered as a whole, the claimed invention described in currently amended claim 142 teaches an isolated or recombinant nucleic acid comprising a polynucleotide sequence of SEQ ID NO: 1, wherein the sequence is greater than 700 base pairs in length, and further wherein the encoded polypeptide is an apoptosis inhibitor.

It is established that a prior art generic disclosure does not make obvious a claim to a species within a particular genus when the prior art generic disclosure does not provide sufficient guidance to select the claimed species from a large number of species within that genus. *See In re Baird*, 16 F.3d 580, 29 USPQ 2d 1550 (Fed. Cir. 1994) (stating that no

anticipation or obviousness for a claim to a specific bisphenol derivative in view of prior art disclosing a generic formula that encompasses that specific bisphenol derivative); *In re Bell*, 991 F.2d 781, 26 USPQ 2d 1529 (Fed. Cir. 1993) (holding claims directed to nucleic acid molecules containing human sequences encoding human insulin-like growth factors patentable despite prior art that suggested a vast number of possible nucleic acid sequences, but gave no indication as to the actual human sequence corresponding to the insulin-like growth factor gene).

In light of the current amendments to claim 142, once the length of the claimed sequences exceeds 700 base pairs, there is absolutely no guidance whatsoever in KATO regarding the sequence of the other base pairs. The number of possible sequences increases geometrically with increasing length of the sequences, once such number exceeds 700 base pairs. However, KATO provides no guidance for determining what the additional bases, other than the 700 base pairs actually specified, should be. This absence of guidance precludes any prediction of the actual sequence with a reasonable probability of success, as required to create a *prima facie* case of obviousness in this context. *In re O'Farrell*, 853 F.2d 894, 903, 7 USPQ 2d 1673, 1681 (Fed. Cir. 1988).

In the instant case, a large genus does not make obvious a relatively small number of species within the genus if there is no guidance for the selection of those species from the large genus. For sequences longer than 700 base pairs, KATO provides no guidance for selecting the correct sequences from the large genus.

The secondary reference, Gregory et al., does not remedy the deficiencies of KATO. Gregory et al. provides no teaching or guidance whatsoever as to the particular sequences of these nucleic acid molecules. Once the sequence is known, Gregory et al. can be combined with the teaching of the sequence for the generation of a construct incorporating a viral vector. However, until the sequence is actually known, Gregory et al. has no effect.

Therefore, Applicant respectfully submits that the proposed combination does not render obvious the sequences of the present invention, because when KATO is combined with Gregory et al., the combined references fail to teach the sequences of the present invention.

Claims 157 and 158 are dependent on claim 142 and are non-obvious as well, since the combination of KATO and Gregory et al. fails to teach the sequences of the present invention.

In light of the above amendments and remarks, Applicant respectfully requests the Examiner to withdraw the rejection of claims 142, 157 and 158 under 35 U.S.C. § 103(a) and allow these claims.

## VII. CLAIM OBJECTIONS

The Examiner has stated that claims 24 and 25 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 24 and 25 are both dependent on claim 17, which is currently amended according to Examiner's recommendation. Therefore, in the current amendment, Applicant canceled claim 24 solely to avoid duplication, and amended claim 25 to claim dependency from currently amended claim 17.

Applicant respectfully submits that current amendments to claims 17, 24 and 25 place claim 17 and all of its dependent claims, including claim 25, in condition for allowance. Therefore, Applicant believes that all of Examiner's objections are met by the current amendments. Allowance of claim 25 is respectfully requested.

VII. CONCLUSION

Applicant respectfully thanks the Examiner for an opportunity to discuss the aforementioned issues in the course of a telephonic interview. In view of the foregoing arguments, Applicant submits that claims 1, 4-28, 76, 77, and 142-163 satisfy the requirements of 35 USC §§ 112 1st paragraph, 112 2nd paragraph, 101, 102(b), and 103(a). Accordingly, Applicant respectfully requests reconsideration and withdrawal of these rejections and requests that the claims be allowed.

Respectfully submitted,

Date: September 6, 2006

Michael B. Farber, Ph.D., Esq.
Reg. No.: 32,612

CATALYST LAW GROUP, APC
9710 Scranton Road, Suite 170
San Diego, California 92121
(858) 450-0099
(858) 450-9834 (Fax)